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#23

FEB 16 1993

Douglas P. Mueller
Wegner, Cantor, Mueller & Player
P.O. Box 18218
Washington, D.C. 20036-8218

Re: Patent Term Extension
Application for
U.S. Patent No. 4,455,297

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,455,297 issued June 19, 1984, which claims the human drug product Acel-Imune, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 1,642 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 27, 1993. The January 27, 1993, notice corrected both an original notice of the regulatory review period published in the Federal Register of May 1, 1992, and a corrected notice published in the Federal Register of May 29, 1992. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (435) + 1,569 \\ &= 1,787 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 17, 1991) when added to the period of extension calculated above (1,787 days) cannot exceed fourteen years. The period of extension is thus limited to December 17, 2005, by operation of 35 USC § 156 (c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on June 19, 2001, the period of extension is the number of days to extend the term of the patent from its expiration date to and including December 17, 2005, or 1,642 days.

The limitations of 35 USC § 156 (g)(6) do not operate to further reduce the period of extension determined above.

U.S. Patent No. 4,455,297

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,455,297 a certificate of extension, under seal, for a period of 1,642 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,455,297
Granted:	June 19, 1984
Applicant:	Yukio Syukuda et al
Owner of Record:	Takeda Chemical Industries, Ltd.
Title:	METHOD FOR PRODUCING PERTUSSIS TOXOID
Classification:	424/92
Product Trade Name:	Acel-Imune
Term Extended:	1,642 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Acel-Imune

FDA Docket No.: 92E - 0115